



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,454	10/04/2004	Hector Knight Castro	1483 WO/US	2287
7590 Tim A Cheatham Mallinckrodt Inc 675 McDonnell Boulevard PO Box 5840 St Louis, MO 63134			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 07/03/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,454

Applicant(s)

KNIGHT CASTRO ET AL.

Examiner

MELISSA PERREIRA

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 6/13/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1,2 and 4-16 are pending in the application. Claim 3 was canceled in the amendment filed 4/18/08. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Priority

1. Receipt is acknowledged of papers (6/13/08) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Oath/Declaration

2. The filing of the substitute Oath and Declaration on 4/17/08 is acknowledged.

Specification

3. The filing of the specification amendment on 4/17/08 is acknowledged

Response to Arguments

4. Applicant's arguments with respect to claims 1,2,4,5 and 16 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1,2,4,5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Supplement to the Manual and Operating Instructions, FDG Synthesizers, Nuclear Interface GmbH, 11/21/01) in view of Dumhaut et al. (US 6,172,207B1) and further in view of Asai et al. (US 5,536,491) and Stone-Elander et al. (5,308,944A).

7. The Supplement to the Manual and Operating Instructions discloses the method of improving the stability (avoiding decomposition) of a FDG solution. The method involves adjusting the pH of the FDG solution to 5.5 with a buffered product. It is important that the pH of the solution does not reach pH=6 because at this pH considerable degradation starts. The Supplement to the Manual and Operating Instructions does not disclose that the FDG is labeled with ¹⁸F, that the buffering agent is citrate or that the solution is autoclaved.

8. Dumhaut et al. (US 6,172,207B1) discloses an ¹⁸F-FDG solution for NMR (example; column 3, line 28; column 6, line 33) where the pH adjustment and isotonicity to injectable standards of the final solution is performed by adding a buffer. The buffer may be a solution of citrate or sodium phosphate, tris or any other injectable buffer

(column 5, lines 44-54). The disclosure states that the collected labeled compound is purified, filtered or sterilized (claim 22).

9. Asai et al. (US 5,536,491) discloses the sterilization of 19F-labeled MRI contrast agents via autoclave (example 30).

10. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the buffer of Dumhaut et al. (i.e. citrate) for another known analogous buffer, such as sodium phosphate for the method of improving the stability of a FDG solution.

11. At the time of the invention it would have been obvious to one skilled in the art to use the known sterilization method of autoclaving a fluorine substituted contrast agent solution of Asai et al. for the sterilization method of Dumhaut et al. (see claim 22) with predictable results, such as providing a sterilized solution for the NMR/MRI. The 18F isotope will be stable against high temperature (as evidenced by Stone-Elander et al., see fig. 7; column 2, lines 22-25) and therefore will be capable of being successfully autoclaved/sterilized.

Conclusion

No claims are allowed at this time.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618